UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

VAXIION THERAPEUTICS, INC., Plaintiff, vs. FOLEY & LARDNER LLP, Defendant.	CASE NO. 07cv280-IEG(RBB) Order Granting in Part and Denying in Part Defendant's Motion for Partial Summary Judgment on Negligence and Breach of Contract Causes of Action [Doc. No. 86]; Denying Motion to Strike [Doc. No. 130]

Defendant Foley & Lardner ("Foley") moves the Court for summary judgment on Plaintiff Vaxiion Therapeutics' ("Vaxiion") first and third causes of action for negligence and breach of contract[1]. Foley argues Vaxiion cannot demonstrate that "but for" the missed international patent filing deadline, it would have obtained greater protection for its minicell[2] technology.

Vaxiion filed an opposition, and also filed objections to certain evidence submitted by Foley in support of its motion. Foley filed a reply and a response to Vaxiion's evidentiary objections, and Foley also moved to strike certain evidence submitted by Vaxiion in support of its opposition. Vaxiion filed an opposition to Foley's motion to strike and Foley filed a reply.

[1]Foley moves for summary judgment on only that portion of Vaxiion's breach of contract claim which is predicated upon the missed PCT filing deadline.

[2]A "minicell" is a small achromosomal (i.e. without chromosomes) cell that is produced by abnormal and unequal division of a parent cell. A minicell is typically smaller than its parent cell. Because a minicell lacks the chromosomes of a parent cell, a minicell cannot and does not reproduce itself.

A hearing was held on November 10, 2008. Based upon the arguments of the parties, for the reasons set forth herein, the Court GRANTS IN PART AND DENIES IN PART Foley's motion. The Court DENIES Foley's motion to strike and overrules all of the parties' evidentiary objections.

Factual Background

The following facts are relevant to Vaxiion's causes of action for negligence/legal malpractice and breach of contract. On May 24, 2001, Foley San Diego attorneys Richard Warburg and Drew Granston filed with the U.S. Patent and Trademark Office ("USPTO") on behalf of Vaxiion[3] a U.S. provisional patent application entitled "Minicell Compositions and Methods" ("First Provisional Application"). [Complaint, ¶¶ 6-7; Declaration of Andrew Granston, Ph.D. in Support of Defendant Foley & Lardner's Motion for Partial Summary Judgment on Vaxiion's Conflicts-Related Claims ("Granston Decl."), Doc. No. 85-26, ¶ 4, Exhibit A.] On February 25, 2002, Foley attorneys Warburg and Granston filed a second provisional application with the same title ("Second Provisional Application"). [Complaint, ¶¶ 6-7; Granston Decl., ¶ 6, Exhibit B.]

To claim priority *in the U.S.* to the First Provisional Application filed on May 24, 2001, Vaxiion had to file a non-provisional U.S. application within one year, or by May 24, 2002. In order to claim priority to the First Provisional Application *outside the U.S.*, Vaxiion had to file a Patent Cooperation Treaty ("PCT") application by the same date.[4] Foley, on behalf of Vaxiion, filed a non-provisional U.S. patent application ("Non-Provisional Application") on May 24, 2002. [Granston Decl., ¶ 7, Exhibit B.] Unfortunately, Foley failed to timely file the PCT Application. Instead, Foley filed the PCT application the next business day, May 28, 2002. [Granston Decl., ¶ 8; Declaration of Richard Warburg, Ph. D. in Support of Foley & Lardner's Motion for Partial

[3]At the time it retained Foley and filed most of the applications at issue in this case, Vaxiion used the name Mpex Bioscience, Inc. For ease and consistency, the Court will refer to the company as "Vaxiion" throughout this Order.

[4]Vaxiion alleges Foley, on behalf of Vaxiion, could have filed a single PCT application that included a claim for rights in the U.S., rather than filing a separate U.S. non-provisional application. Whether Foley should have filed the PCT, and whether the PCT would have given Vaxiion the same rights in the U.S. as the non-provisional application Foley did file, are not at issue in this motion.

Summary Judgment on Vaxiion's Conflicts-Related Claim ("Warburg Decl."), Doc. No. 85-36, ¶ 4.]

Vaxiion alleges that as a result of the missed PCT Application deadline, Vaxiion could not claim priority in its pursuit of international patent rights to the May 24, 2001 First Provisional Application. Instead, Vaxiion is able to claim priority only to its February 25, 2002 Second Provisional Application. [Complaint, ¶ 10.] On October 15, 2001, a competitor in the biotech field, an Australia company by the name of EngenIC, filed a provisional U.S. application, titled "Intact Minicells as Vectors for DNA Transfer and Gene Therapy In Vitro and In Vivo." [Id.] EnGeneIC then timely filed its PCT Application on October 15, 2002. As a result, the EnGeneIC PCT Application claims priority to Vaxiion's PCT Application in the international arena. [Id.] EnGeneIC has nationalized the PCT filing[5] in Australia and on August 23, 2007 obtained an Australia patent. [Declaration of Ryan Lindsey in Support of Foley & Lardner's Motion for Partial Summary Judgment on Negligence and Contract Claims ("Lindsey Decl."), Doc. No. 86-25, ¶¶ 33 and 34, Exhibits GG and HH.] EnGeneIC has also nationalized its PCT filing in Europe, Canada, and Japan, but those proceedings remain pending.

On September 22, 2004, Vaxiion requested entry into the national phase in Australia. [Lindsey Decl., Exhibit Y.] Although Vaxiion's original PCT Application contained 464 claims, Vaxiion submitted 31 new claims to the Australian Office. Vaxiion subsequently canceled three of those claims in response to the examiner's finding the three claims were not "fairly based on the application as originally filed." [Lindsey Decl., Exhibits BB and Exhibit CC.]

On April 26, 2007, the Australia Patent Office issued a report rejecting all 28 of Vaxiion's pending claims for lack of unity of invention.[6] [Exhibit H-5 in Support of Vaxiion's Opposition to Foley & Lardner's Motion for Partial Summary Judgment, Doc. No. 113-15.] The examiner

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[5]The filing of a PCT Application does not afford the applicant any particular international patent rights. Instead, the applicant must "nationalize" the application by pursuing patent claims in individual countries.

[6]"Unity of invention" refers to the idea that an application should relate to only one invention, or alternatively to a group of inventions which are linked in such a way as to constitute a singular general inventive concept. PCT Rule 13 (available at www.uspto.gov/web/offices/pac/mpep/documents/1800_1850.htm).

further noted claims 13 and 27 were "not novel and did not involve an inventive step" in light of a 1992 article authored by Khachatourians. Finally, the examiner found claims 1-5, 7-9, 13-22, and 24-28 were not novel in light of the EnGeneIC PCT Application. [Id., p. 2.] In response to the examiner's objections, Vaxiion submitted ten amended claims for examination on November 22, 2007. [Exhibit H-6 in Support of Vaxiion's Opposition to Foley & Lardner's Motion for Partial Summary Judgment, Doc. No. 113-16 (also found at Lindsey Decl., Exhibit DD).]

In order to overcome the examiner's citation to the EnGeneIC prior application, Vaxiion amended the identified claims, canceling a number of the claims without prejudice and amending others to work around the limitations posed by the EnGeneIC application. For example, Vaxiion amended claim 7 (which became claim 1) to read "A minicell comprising a nucleic acid, wherein said nucleic acid comprises eukaryotic expression sequences and eubacterial expression sequences, each of which is independently operable linked to the same ORF." [Exhibit H-6, p. 4.] Vaxiion argues this amendment is significant because while the application originally permitted Vaxiion to use a platform including *either* eukaryotic or eubacterial expression sequences, consistent with the rights Vaxiion holds in the United States, Vaxiion is now limited to a platform which utilizes both expressions operating in tandem. The Australian Patent Office ultimately accepted Vaxiion's amended claims on November 26, 2007. [Lindsey Decl., Exhibit EE.]

In addition to Australia, Vaxiion has pursued patent rights in Europe and Canada. However, Vaxxion argues its claims in those countries have been significantly limited as a result of the prior-filed EnGeneIC PCT application. Vaxiion requested entry into the European Phase ("EPO") based upon its PCT application on September 22, 2004. [Lindsey Decl., Exhibit Y, Doc. No. 86-45.] Vaxiion sought examination of only 18 of the original 464 claims set forth in the PCT Application. Vaxiion's EPO Application is currently being examined, and none of Vaxiion's claims have been restricted or rejected in any way. Vaxiion also requested entry into the national phase in Canada on August 23, 2005. [Lindsey Decl., Exhibit Z, Doc. No. 86-46.] On May 24, 2007, Vaxiion substituted 39 new claims for all of its pending Canadian claims. [Lindsey Decl., Exhibit AA, Doc. No. 86-47.] Vaxiion's Canadian application is currently being examined, and to date none of the 39 claims have been rejected or restricted in any way.

Vaxiion alleges the detriment it suffered in the international arena as a result of the missed PCT filing deadline is demonstrated by the way the patent process progressed in the United States. Vaxiion argues that in the United States, where Foley timely filed its non-provisional application, Vaxiion was able to claim priority for its invention to the First Provisional Application. The USPTO issued a patent to Vaxiion titled "Eubacterial Minicells and their use vectors for nucleic acid delivery and expression" on February 27, 2006. [Complaint, ¶ 11; Declaration of Ryan E. Lindsey in Support of Foley & Lardner's Motion for Partial Summary Judgment on Plaintiff's Negligence and Breach of Contract Claims for Absence of Proof of Causation and/or Damages ("Lindsey Decl."), Doc. No. 86-24, Exhibit G.] Although EnGeneIC also pursued patent rights in the United States with regard to its minicell technology, on July 25, 2007, the PTO rejected EnGeneIC's application based upon Vaxiion's then-issued '105 Patent. [Declaration of R. Brian McCaslin in Support of Defendant Foley & Lardner's Motion for Partial Summary Judgment on Conflicts-Related Claims ("McCaslin Decl."), ¶ 6, Exhibit E.]

Discussion

1. Legal Standard

Vaxiion's claim against Foley for legal malpractice requires evidence of four elements:

> (1) the duty of the attorney to use such skill, prudence, and diligence as members of his or her profession commonly possess and exercise; (2) a breach of that duty; (3) a proximate causal connection between the breach and the resulting injury; and (4) actual loss or damage resulting from the attorney's negligence.

Coscia v. McKenna & Cuneo, 25 Cal. 4th 1194, 1199 (2001). In this motion, Foley moves for summary judgment on Vaxiion's first and third causes of action, for negligence and breach of contract. Foley does not dispute it owed a duty of care to Vaxiion, but argues there is an issue of fact as to whether Foley breached that duty.[7] As a result, Foley moves for summary judgment *only on the basis that Vaxiion cannot demonstrate it suffered any actual injury caused by the alleged negligence*.

In Viner v. Sweet, 30 Cal. 4th 1232 (2003), the California Supreme Court clarified the

[7]Vaxiion has also moved for summary judgment on the negligence and breach of fiduciary duty causes of action, arguing Foley breached its duty of care and its fiduciary duties as a matter of law. This motion is resolved by separate order of the Court.

standard of causation applicable to all actions for legal malpractice. In order to prove proximate cause in a legal malpractice action, the plaintiff must demonstrate "that *but for* the alleged negligence of the defendant attorney, the plaintiff would have obtained a more favorable" outcome. 30 Cal. 4th at 1241 (emphasis in original). The causation inquiry has been likened to a trial-within-a-trial because "the crucial causation inquiry is *what would have happened* if the defendant attorney had not been negligent." Id. at 1242 (emphasis in original). The parties point to no different standard of causation applicable to the breach of contract cause of action, which is based entirely on the same conduct Vaxiion alleges supports the legal malpractice claim.

The plaintiff need not prove causation with absolute certainty, but instead "need only 'introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a cause in fact of the result'." Id. at 1243 (quoting Ortega v. Kmart Corp., 26 Cal. 4th 1200, 1205 (2001)). This is an "objective approach" which requires the factfinder to determine what the result should have been in the underlying proceeding or matter in the absence of counsel's negligence. Church v. Jamison, 143 Cal. App. 4th 1568, 1585 (2006).

Ordinarily, the question of whether plaintiff has demonstrated the outcome would "more likely than not" have been more favorable in the absence of the lawyer's alleged negligence is an issue of fact which cannot be resolved by summary judgment. Ambriz v. Kelegian, 146 Cal. App. 4th 1519, 1531-32 (2007) (in legal malpractice action against attorney whose negligence allegedly caused plaintiff to lose her premises liability case, the appellate court reversed the trial court's grant of summary judgment finding there was an issue of fact as to whether plaintiff would have lost her underlying premises liability action even if her attorneys had provided adequate representation); see also Dawson v. Toledano, 109 Cal. App. 4th 387, 396 (2003) (in action alleging legal malpractice against appellate attorney, appellate court reversed trial court's grant of summary judgment finding the facts did not demonstrate one of those "very rare" instances in which it was appropriate to grant summary judgment on issue of causation).

2. The Causation Inquiry in This Case

Foley argues the only way for the Court to determine whether Vaxiion has suffered any

injury *caused by* the missed PCT deadline on both Vaxiion's negligence and breach of contract claims is to determine whether there were any patent claims Vaxiion actually lost in the international arena by virtue of the late filing. Foley argues the Court must then also determine whether Vaxiion would have been entitled to patent the technology in those claims even if the PCT had been timely filed. Foley argues the evidence makes clear the only non-U.S. patent claims Vaxiion intended to prosecute are those which it actually prosecuted and obtained in Australia, as well as those Vaxiion is pursuing in Canada and Europe. Foley insists the *only* way to analyze what Vaxiion lost by virtue of the missed PCT deadline is to conduct a claim-by-claim analysis of the U.S., Australia, Canadian, and European patent applications.

By contrast, Vaxiion argues the Court can determine what would have happened "but for" Foley's alleged negligence by looking at the patent claims EnGeneIC ultimately secured in Australia and comparing those claims to Vaxiion's underlying technology. Vaxiion argues that if Foley had timely filed the PCT Application, it would have been entitled to the same broad protection internationally as it secured in the United States. Vaxiion contends it was instead required to narrow the scope of the protection it pursued in Australia as a result of the late filed PCT application and the intervening prior filed EnGeneIC PCT.

Foley argues there are three primary reasons Vaxiion could not have validly claimed priority for many of its sought-after claims in the international arena, even assuming Foley timely filed the PCT on its behalf. Notwithstanding the missed filing deadline, Foley argues Vaxiion does not have the right to claim priority with regard to many of the claims it sought to have issued in Australia, and seeks to have issued in Canada and Europe, because those claims:

a. cover subject matter expressly disclaimed by the First Provisional Application (i.e. contain as an essential element that the claimed minicells comprise an "immunogenic compound" and/or generate an "immunogenic response");

b. cover subject matter not enabled by[8] or disclosed in the First Provisional Application (i.e. claims which refer to Example 19 from the PCT Application as providing support for enablement); or

c. cover subject matter which the U.S examiner found was not enabled by or disclosed in the First Provisional Application (i.e. claims including the essential element

[8]A patent claim is "enabled" when a person skilled in the art can make or use the disclosed invention. 35 U.S.C. § 112.

> "wherein said cell displays a ligand specifically recognized by a binding moiety"; claims seeking protection for "minicells" generally, rather than eubacterial minicells; claims referring to "nucleic acids" or "contents" generally, rather than double-stranded DNA; or claims referencing *separate* molecules containing eukaryotic and eubacterial sequences).

Foley argues Vaxiion cannot show that "but for" Foley's alleged negligence, it would have obtained greater protection of its intellectual property in the international arena. Therefore, Foley argues it is entitled to summary judgment on the negligence and breach of contract causes of action.

a. Does the language of the First Provisional Application, defining "biologically active," bar Vaxiion from arguing it would have been entitled to obtain non-U.S. patent coverage for compositions eliciting an immunoreactive/immunogenic response?

Vaxiion's submitted EP claims 1-6 and 16-18, and Canadian claims 6-15, 21, and 26-37 each include the essential element that the claimed minicells comprise an "immunogenic compound" and/or generate an "immunogenic response." [Lindsey Decl., Exhibits Y and Z.] Similarly, rejected Australian claims 1-6, 22-23, and 26-27, required "immunogenic" activity. [Lindsey Decl., Exhibit AA.] Foley argues Vaxiion is precluded from arguing any damage from any loss of international patent claims containing as an element "immunogenic compounds" or "immunogenic responses," because this subject matter was expressly disclaimed by Vaxiion's First Provisional Application.

The First Provisional Application defined "biologically active" as follows:

> The term "biologically active" (synonymous with "bioactive") as it is used herein indicates that a compound, moiety or minicell has a biological effect, or that it modifies, causes, promotes, enhances, blocks, reduces, limits the production or activity of, or reacts with or binds to, an endogenous molecule that has a biological effect. A "biological effect" may be but is not limited to one that stimulates or causes an immunoreactive response; one that impacts a biological process in an animal; one that impacts a biological process in a pathogen or parasite; one that generates or causes to be generated a detectable signal; and the like. Biologically active compounds, moieties or minicells may be used in therapeutic and diagnostic methods and compositions. Biologically active compounds, moieties or minicells act to cause or stimulate a desired effect upon an animal. Non-limiting examples of desired effects include, for example, preventing, treating, or curing a disease or condition in an animal suffering therefrom; limiting the growth of or killing a pathogen in an animal infected threby; augmenting the phenotype or genotype of an animal; or diagnosing a disease or disorder in an animal. *However, as is used herein, the term "bioactive" specifically excludes stimulating an immunoreactive response in an animal.*

[Lindsey Decl., Exhibit A, p. 6 (emphasis added).] The Second Provisional Application deleted

from of the definition of "biologically active" or "bioactive" the italicized last sentence quoted above, which excluded stimulating an immunoreactive response. The Second Provisional Application further added to the definition of "biologically active" an example indicating that a biologically active composition, complex, or compound *could act* to "stimulat[e] a prophylactic immunoreactive response in an animal ...." [Lindsey Decl., Exhibit C, p. 7.]

Based upon the differing language in the First and Second Provisional Applications, Foley's expert has opined that Vaxiion has no claim in the international arena to a minicell-based vaccine. [Declaration of Mark A. Kay in Support of Foley & Lardner's Motion for Partial Summary Judgment on Negligence ("Kay Decl."), Doc. No. 86-20, pp. 30-32.] Foley points out that Vaxiion recognized early on that the exclusionary phrase in the First Provisional Application could limit its ability to develop DNA minicell vaccine applications. In fact, Vaxiion's own documents show it considered the "primary risk" to the company's development of rights in the United States was the limitation in phrasing in the First Provisional Application relating to immune applications. [Declaration of Ryan Lindsey in Support of Foley & Lardner's Reply Regarding Motion for Partial Summary Judgment on Negligence ("Lindsey Reply Decl."), Exhibit B, Doc. No. 136-3, pp.1, 3, 8.]

Unfortunately, Foley does not counter Vaxiion's argument with citation to anything in the record. In the "chart" at the beginning of its points and authorities in opposition to Foley's argument, Vaxiion simply states it is "not true" that the First Provisional Application did not include immunogenic responses. The entirety of Vaxiion's response to Foley's detailed argument and analysis follows:

> Vaxiion's invention is a minicell delivery platform. A properly drafted patent application is required to be drafted as broadly as possible in order to provide the maximum protection for the inventor. In this case, the application relates to a minicell "platform" that covers nucleic acid delivery, targeted nucleic acid delivery, targeted drug delivery, and bio-imaging, which clearly includes immunogenic response. Furthermore, skewed focus on one isolated potential use of the platform is misguided and misleading.

[Vaxiion's Memorandum in Opposition to Foley & Lardner's Motion for Partial Summary Judgment on Negligence, Doc. No. 113, p. 7.] Vaxiion does not cite to its expert reports or anything else in the record to support its contention the First Provisional Application included a

claim to technology related to the use of minicells to elicit an immunogenic response.

The Court has, however, reviewed the initial and rebuttal reports of Vaxiion's expert, William Respess, as well as his declaration filed in support of Vaxiion's opposition to this motion. [Lindsey Decl., Exhibits JJ and KK, Doc. Nos. 86-56 and 86-57; Declaration of William Respess in Support of Opposition to Foley & Lardner's Motion for Partial Summary Judgment on Negligence ("Respess Decl."), Doc. No. 113-24.] Dr. Respess's initial report did not directly address the question of whether the First Provisional Application included a claim for compounds which could act to stimulate an immunogenic response. In his rebuttal report, however, Dr. Respess opined that the specification in the First Provisional Application, stating the compound must not stimulate an immunoreactive response, is simply an ambiguity resolved by other portions of the Application. [Lindsey Decl., Exhibit KK, pp. 11-13.] Dr. Respess points out the first two sentences of the same paragraph states the "biological effect" is defined to *include* "one that causes an immunoreactive response." [Lindsey Decl., Exhibit A, p.6.] In addition, the last sentence on page 75 of the First Provisional Application states

> Those skilled in the art will appreciate that when the compositions of the present invention are administered as agents to achieve a particular desired biological result, which may include a therapeutic or protective effect(s) (including vaccination), it may be necessary to combine the fusion proteins of the invention with a suitable pharmaceutical carrier.

[Id., p. 75.] Furthermore, Dr. Respess points out in his report that the inventors dealt with the ambiguity in later versions of the specification by deleting the language.

What is most persuasive in rebutting Foley's argument that Vaxiion's First Provisional Application did not disclose the potential use of the invention for immunogenic purposes, however, is the fact the USPTO *issued* the '105 Patent, which contains claims to technology including possible immunogenic uses of minicells. [Lindsey Decl., Exhibit G, Doc. No. 90, columns 21, 22, 215-219]. Although the U.S. examiner initially expressed doubt whether the invention claimed in the First Provisional Application included immunogenic uses of minicells, Vaxiion successfully overcame the U.S. examiner's objections. But for the missed PCT Application filing deadline, Vaxiion would have been able to make a similar argument in Australia, Canada, and Europe without also being required to demonstrate its invention was novel

over the EnGeneIC prior art.

Vaxiion's success before the USPTO does not necessarily guarantee it would have also been successful in its international patent prosecutions. However, Vaxiion's success in the U.S. does demonstrate there is a reasonable basis upon which a patent examiner in Australia, Canada, and/or Europe could conclude Vaxiion was entitled to patent protection for immunogenic uses of minicells. As a result, the Court finds there are genuine issues of material fact precluding summary judgment as to whether the late filing of the PCT application caused Vaxiion to lose its international patent rights to use minicell technology for immunogenic purposes.

b. Was Vaxiion's invention sufficiently enabled by the First Provisional Application so as to allow the factfinder to consider whether Vaxiion suffered injury from the late filing of the PCT Application?

Vaxiion's submitted EP claims 1-6 and 13-18, its submitted Canadian claims 5-6, 23-24, and 26-39, and its rejected Australian claims 1-6 and 20-23, all rely upon "Example 19" of Vaxiion's PCT Application for support. This example first appeared in Vaxiiion's Second Provisional Application. [Lindsey Decl., Exhibit C, Doc. No. 87, pp. 267-269.] As a result, Foley argues Vaxiion could not have been entitled to the priority filing date of Vaxiion's First Provisional Application, even assuming the PCT Application was timely filed, because Vaxiion's invention was not enabled by the First Provisional Application. Foley's argument is supported by the declarations of its experts, both of whom opine the submitted or rejected claims are not enabled by the First Provisional Application. [Kay Decl., ¶¶ 4-5; Declaration of Chris Mercer in Support of Foley & Lardner's Motion for Partial Summary Judgment on Negligence, Doc. No. 86-23, ¶ 114.] Foley reviews in detail the prosecution history of Vaxiion's U.S. Applications, and points out each instance where the examiner found the proposed claims not to be enabled. [Foley & Lardner's Points and Authorities in Support of Partial Summary Judgment on Negligence, Doc. No. 86, pp. 7-12, 35-37.]

In opposition, Vaxiion submits the declarations of its experts. [Respess Decl., Doc. No. 113-24; Declaration of Roy Curtiss in Opposition to Foley & Lardner's Motion for Partial Summary Judgment on Negligence ("Curtiss Decl."), Doc. No. 113-22; Declaration of Harry Manbeck in Opposition to Foley & Lardner's Motion for Partial Summary Judgment on

Negligence ("Manbeck Decl."), Doc. No. 113-23.] Mr. Curtiss points out that the USPTO issued the '105 Patent with a priority date based upon the First Provisional Application, without any objection that the EnGeneIC PCT application was prior art. If the examiner had found the invention described by Vaxiion's applications was enabled only by the Second Provisional Application, Vaxiion would not have been entitled to priority back to the First Provisional Application, and the EnGeneIC PCT Application would have been prior art. [Curtis Decl., ¶ 8.] Vaxiion's other experts similarly opine that if Vaxiion's First Provisional Application did not enable the broad claims of Vaxiion's engineered minicell technology, the U.S. examiner would have rejected the broad claims of Vaxion's patent on the basis that EnGeneIC's PCT Application was prior art. [Manbeck Decl., ¶¶ 6-12; Declaration of William Respess in Opposition to Foley & Lardner's Motion for Partial Summary Judgment on Negligence, Doc. No. 113-24, ¶¶ 11-20.]

Notwithstanding the U.S. examiner's initial objections to the application based upon lack of enablement, the USPTO ultimately issued the '105 Patent with a priority date back to the filing of the First Provisional Application. Again, the Court finds there are genuine issues of material fact as to whether, if the PCT Application had been timely filed, Vaxiion would have been able to demonstrate in its international patent prosecution processes that its claimed invention was enabled by the First Provisional Application.

c. Does the U.S. examiner's limitation of Vaxiion's patent claims, to exclude certain subject matter which the U.S examiner found was not enabled or disclosed in the First Provisional Application bar Vaxiion from claiming it suffered any damage from exclusion of those claims in the international patent arena?

Foley argues Vaxiion is barred from arguing it suffered any injury resulting from the loss of any international patent rights in subject areas in which the U.S examiner found the invention was not enabled or disclosed in the First Provisional Application. For example, Foley argues Vaxiion's proposed EP claims 1-6 and 10, corresponding Canadian claims 10-15 and 18, and rejected Australian claims 1-6, contain the essential element "wherein said cell displays a ligand specifically recognized by a binding moiety ...." However, in the prosecution of Vaxiion's U.S. patent rights, the examiner found that a "binding moiety" was not enabled by any of Vaxiion's applications. As a result, in April 2004, Vaxiion canceled all its U.S. claims containing the "binding moiety" element. [Lindsey Decl., Exhibit I.]

Similarly, Foley argues Vaxiion's proposed EP claims 1, 3-8, and 10-18, proposed Canadian claims 1-2, 6-20, and 22-39, and rejected Australian claims 1, 3-6, 13, 15-18, 20-23, and 26-27, are replete with references to "minicells" generally, rather than eubacterial minicells, which were the *only* type of minicells found by the U.S. examiner to be enabled in the Applications. Many of Vaxiion's non-U.S. claims, including EP claims 1-11, 13-14, and 16-18, Canadian claims 1-4, 6-22, and 26-39, and Australian rejected claims 1-6, 13-18, 22-23, and 26-27 also refer to "nucleic acids" and/or "contents" generally. Foley argues, however, the only type of nucleic acid found by the U.S. examiner to be enabled by the U.S. Applications was double-stranded DNA. Finally, Foley argues many of Vaxiion's EP and Canadian claims reference *separate* nucleic acid molecules containing eukaryotic and eubacterial sequences (EP claims 5-12, 18, Canadian claims 2-14, 14-15, 30, 34-39, and rejected Australian claims 5-6), even though the U.S. examiner expressly found that such element was not enabled. Foley argues Vaxiion canceled all its U.S. claims containing any of these elements in April 2004. [Lindsey Decl. Exhibit I.] Foley argues Vaxiion cannot claim it lost any international patent rights stemming from the late-filed PCT Application insofar as Vaxiion seeks to claim an invention with the above-detailed essential elements.

In its opposition, Vaxiion states in its introductory "chart" that "[t]he United States patent issued sufficiently broad to block EnGeneIC's United States application, demonstrating the overlapping nature of the applications." Vaxiion does not cite to any declaration by its experts establishing that it has the right to pursue damages for the alleged loss of the patent rights encompassing these essential elements. The Court has been unable to find any portion of the reports or declarations of Vaxiion's experts submitted in opposition to the summary judgment motions which address this issue.

Vaxiion has not explained how the late-filed PCT Application caused it to lose the right to pursue international patent protection for claims containing the essential elements of "binding moiety," claims which refer to minicells generally rather than eubacterial minicells, claims which refer to "nucleic acids" or "contents" generally rather than double-stranded DNA, and claims which refer to separate nucleic acid molecules. Vaxiion has provided no evidence demonstrating

it would have been able to obtain international patent rights for claims containing these additional elements "but for" Foley's alleged negligence. Therefore, Foley is entitled to partial summary judgment with regard to this portion of Vaxiion's negligence and breach of contract claims.

3. Additional arguments

Foley raises two additional arguments in its motion which Vaxiion does not address in its opposition. The Court, however, finds that neither of these arguments justify partial summary judgment.

i. Did EnGeneIC's PCT application destroy the novelty of Vaxiion's non-U.S. claims?

Foley argues the EnGeneIC PCT application does not destroy the novelty of Vaxiion's prosecuted non-U.S. claims, such that Vaxiion cannot show it suffered damage as a result of the late-filed PCT Application. In particular, Foley points to the fact Vaxiion was able to explain to the Australian examiner how Vaxiion's proposed claims differ from the claims set forth in EnGeneIC's PCT so as to overcome the examiner's objections. Foley argues that Vaxiion was able to obtain some non-U.S. patent claims, and Vaxiion has failed to identify any other particular patent claim which it was unable to obtain because of the citation to EnGeneIC's PCT as prior art. Foley points out no Vaxiion expert witness actually compared the Vaxiion EP or Canadian claims with the EnGeneIC Provisional Application to determine whether the two completely overlap.

Foley's argument that EnGeneIC's PCT application does not destroy the novelty of Vaxiion's invention, or in any way limit Vaxiion's ability to prosecute its non-U.S. claims, is foreclosed by the manner in which the Australian prosecution proceeded. As explained above, the Australian examiner initially rejected Vaxiion's submitted claims 1-5, 7-9, 13-22, and 24-28 as not novel in light of the EnGeneIC PCT Application. [Id., p. 2.] In response to the examiner's objections, Vaxiion submitted ten amended claims for examination on November 22, 2007. [Exhibit H-6 in Support of Vaxiion's Opposition to Foley & Lardner's Motion for Partial Summary Judgment, Doc. No. 113-16 (also found at Lindsey Decl., Exhibit DD).] The fact Vaxiion was forced to narrow its claims in the Australian prosecution creates a genuine issue of material fact as to whether the late PCT Application more likely than not resulted in a narrowing

of Vaxiion's ability to seek international patent protection.[9]

ii. Can Vaxiion show actual loss of damages with regard to the still pending European and Canadian claims?

Foley argues any harm flowing from the late-filed PCT Application is purely speculative with regard to Vaxiion's ability to obtain protection for its invention in Europe and Canada because those claims are still being examined, have not been rejected or limited in any way, and and may still issue. Foley also argues Vaxiion cannot show it suffered any damage with regard to the ten patent claims actually accepted by the Australian office.

Foley cites cases which stand for the proposition that a plaintiff seeking to avoid summary judgment in a legal malpractice action on the issue of causation must proffer some evidence to establish plaintiff suffered some actual damage from the attorney's negligence. Marshak v. Ballesteros, 72 Cal. App. 4th 1514, 1518 (1999) (trial court properly granted summary judgment on legal malpractice claim where plaintiff presented no evidence demonstrating the underlying case was worth more than it settled for); Thompson v. Halvonik, 36 Cal. App. 4th 675 (1995) (same). Both of these cases, however, concerned the valuation of damages where the underlying case settled and the plaintiff thought he/she should have gotten a better settlement in the absence of attorney malpractice. Neither case alters the general standard of causation which applies to legal malpractice claims – that the plaintiff need not prove causation with absolute certainty, but instead "need only 'introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a cause in fact of the result'." Viner, 30 Cal. 4th at 1243 (quoting Ortega., 26 Cal. 4th at 1205).

In this case, Vaxiion has submitted evidence demonstrating it was required to limit the scope of its non-U.S. patent claims to work around the EnGeneIC prior application. Vaxiion has

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[9]Although there are genuine issues of material fact precluding summary judgment, the Court notes that the approach of Vaxiion's experts, comparing the claims actually secured by EnGeneIC to hypothetical claims which Vaxiion may have asserted if Foley had timely filed the PCT Application, does not provide a clear basis to evaluate the nature and value of damages Vaxiion may have suffered. At the time of trial, Vaxiion will need to identify particular patent claims which it actually pursued or intended to pursue in Australia, Canada, or Europe and was required to amend or delete because of the existence of the EnGeneIC PCT Application. To the extent this requires Vaxiion's experts to supplement their prior reports, the parties should contact the magistrate judge to discuss a timetable for such supplementation.

also shown that EnGeneIC's United States patent rights were limited as a result of Vaxiion's prior application. There is no reason to believe Vaxiion would not have had the same success in its prosecution of its international patent rights as it had in the United States if Foley had timely filed the PCT application maintaining Vaxiion's right to priority. There is certainly a "reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a cause in fact of the result."

Foley's Motion to Strike and Evidentiary Objections of both parties

Foley has filed a motion to strike undisclosed expert opinions by Vaxiion's experts provided in opposition to this motion for summary judgment. Foley also moves to strike evidence and argument regarding alleged subsequent remedial measures. Finally, Foley objects to, but does not move to strike, a portion of attorney Andrew Granston's deposition testimony cited by Vaxiion in opposition to the motion. Vaxiion has filed its own evidentiary objections regarding evidence submitted by Foley in its motion.

1. Vaxiion's motion to strike expert declarations

Foley objects that the declarations of Vaxiion's experts, Roy Curtiss III, William Respess, and Harry Manbeck, Jr. all contain a claim-by-claim analysis of Vaxiion's alleged lost patent rights – an analysis not done previously by any of these experts. Foley argues that because the experts are offering new, never previously disclosed opinions, the Court must strike the declarations.

In reaching its determination that there are genuine issues of material fact precluding summary judgment, the Court has not relied substantially upon the objected-to portions of the declarations of Vaxiion's experts. Furthermore, although Foley argues Vaxiion's experts' opinions were not previously expressed in their original reports and depositions, a comparison of the declarations with the reports does not support this assertion. Although the Vaxiion's experts' reports may not have contained each and every individual opinion now contained in their declarations, the substance of Vaxiion's experts' opinions remain unchanged. The Court denies Foley's motion to strike Vaxiion's experts' declarations filed in opposition to the motion for partial summary judgment.

2. Vaxiion's motion to strike subsequent remedial measures

Foley next moves to strike evidence submitted by Vaxiion regarding certain seminars given at Foley within a month after the missed Vaxiion PCT filing deadline, and shortly after Foley discovered its joint representation of EnGeneIC. Foley argues the evidence falls within the scope of Fed. R. Evid. 407 and is inadmissible as subsequent remedial measures.

The Court need not decide whether the evidence is admissible under Fed. R. Evid. 407. Vaxiion submits the evidence regarding the Foley seminars in order to establish Foley breached its duty of care toward Vaxiion, an issue not relevant to the current motion. Because the evidence is not relevant to the issues in the motion, and has not been considered by the Court with regard to the determination of the motion, the Court denies as moot Foley's motion to strike.

3. Foley's objection to deposition testimony of Andrew Granston

Foley also objects to, but does not move to strike, Vaxiion's Exhibit C in opposition to Foley & Lardner's partial motion for summary judgment. This exhibit contains deposition testimony by Attorney Andrew Granston stating he did not have in his possession before 10:00 p.m. on May 24, 2002 a document that satisfied the PCT filing requirements. Foley also objects to certain testimony by Mr. Granston to the effect that if he had filed the improperly formatted application it may have preserved the priority date. Foley objects this testimony calls for a legal conclusion.

Regardless of whether the testimony calls for a legal conclusion, it is irrelevant to the arguments and claims before the Court with regard to this summary judgment motion. Any testimony by Granston regarding the PCT application, or the potential implication of filing the document in an improper format, goes only to the issue of whether there was a breach of duty. The Court overrules as moot Foley's objection.

4. Vaxiion's objection to various portions of evidence

Vaxiion has filed a document objecting to various portions of deposition testimony and declarations submitted by Foley in support of its motion. Vaxiion's objections are based upon various Rules of Evidence. Upon review, none of Vaxiion's evidentiary objections go to the reliability of evidence upon which the Court based its decision. Vaxiion's evidentiary objections

are overruled as moot.

Conclusion

For the reasons set forth herein, the Court GRANTS IN PART AND DENIES IN PART Foley's motion for partial summary judgment on Vaxiion's negligence and breach of contract claims [Doc. No. 86]. The Court GRANTS Foley's motion for partial summary judgment on any claims by Vaxiion that the late-filed PCT Application caused it to lose the right to pursue international patent protection for claims containing the essential elements of "binding moiety," claims which refer to minicells generally rather than eubacterial minicells, claims which refer to "nucleic acids" or "contents" generally rather than double-stranded DNA, and claims which refer to separate nucleic acid molecules. The Court DENIES the remainder of Foley's motion for partial summary judgment on Vaxiion's first and third causes of action for negligence and breach of contract. The Court DENIES Foley's motion to strike [Doc. No. 130] and overrules all evidentiary objections.

IT IS SO ORDERED.

DATED: December 8, 2008

IRMA E. GONZALEZ, Chief Judge
United States District Court